IV. The Rejection of claims 1, 2 and 10 Under 35 U.S.C. § 101

In the Office Action at pages 2-4, the Examiner has rejected claims 1, 2 and 10 under 35 U.S.C. § 101 as allegedly not being supported by either specific and/or substantial utility. Applicants respectfully traverse the rejection.

In support of this rejection the Examiner asserts:

> It is not apparent from the specification that the claimed SEQ ID Numbers encode a product which has the same function as a glutamyl tRNA reductase to which the Applicants assert that they are claiming. According to the table on page 255 of the specification, the claimed SEQ ID Numbers show some degree of homology based on BLASTN search. Absent evidence to the contrary by applicants, it is assumed that the claimed nucleic acids do not exhibit the same function as glutamyl tRNA reductase enzyme and thus, fails to demonstrate specific utility as set forth above.

Office Action, page 4, lines 3-9. Applicants respectfully disagree with these assertions.

It is clearly established in the law that an Examiner has the initial burden of challenging an assertion of utility in the disclosure. The Federal Circuit explicitly addressed this issue in *In re Brana*, stating, "[o]nly after the PTO *provides evidence* showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the inventor's asserted utility." *In re Brana,* 51 F.3d 1560, 1566 (Fed. Cir. 1995). In the present application Applicants have asserted that the claimed nucleic acid sequences code for a glutamyl tRNA reductase, and have provided evidence in the form of BLASTN results to that effect. Based on these BLASTN results, one of ordinary skill in that art would immediately appreciate the usefulness of the claimed nucleic acid molecules. *See also, In re Cortright,* 165

F.3d 1353 (Fed. Cir. 1999) (In cases where the applicant has made an assertion of utility, the PTO cannot reject for lack of utility unless it has reason to doubt the objective truth of the statements contained in the written description.).

Even if, *arguendo,* the Examiner did question the objective truth of Applicant's assertion of utility, in order to make a proper rejection the Examiner must make a *prima facie* showing of no utility. A requirement for this showing is to show support for factual findings that the Examiner relied upon in reaching this conclusion. M.P.E.P. 706.03(a)(1). *See also Brana* at 1466 (the PTO must provide evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility). In the present case, the Examiner has provided no support or factual findings suggesting that the claimed nucleic acid molecules do not have the asserted utility. Rather, the Examiner relies on allegations, without support, that the nucleic acids of the invention may not encode full-length proteins. As such, the Examiner's rejection fails to meet the *prima facie* standard, and is not proper.

Applicants have asserted substantial utilities for the claimed nucleic acids of the invention, and absent any evidence to the contrary this assertion must be accepted. *Cortright* at 1357. Applicants have asserted a number of utilities for which the nucleic acids of the invention can be used. These include, but are not limited to, determining the expression levels of the enzymes involved in the tetrapyrole pathway in plants (page 40, line 7, through page 43, line 20); detecting mutations in the genes encoding these enzymes (page 43, line 21, through page 46, line 7); and producing plants with altered expression of tetrapyrole pathway enzymes (page 46, line 8, through page 51, line 20). As such, Applicants do not need to produce any further evidence of utility. *See In re Chilowsky* 229 F.2d 457, 462 (CCPA 1956)

(No further evidence of utility is required if the alleged utility conforms to the known laws of physics and chemistry).

Therefore, the rejection of claims 1, 2 and 10 under 35 U.S.C. 101 is not proper. Reconsideration and withdrawal of this rejection is respectfully requested.

V. The Rejection of Claims 1, 2 and 10 Under 35 U.S.C. § 112, First Paragraph

In the Office Action, at pages 4-7, the Examiner has maintiained the rejection of claims 1, 2 and 10 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an specific and/or substantial utility. Applicants respectfully traverse this rejection.

As set forth above, Applicants have asserted a substantial and specific utility for the nucleic acid molecules of the invention. As the court stated in *In re Marzocchi*, a properly asserted utility "***must*** be taken as in compliance with the enabling requirement of the first paragraph of § 112 unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." *In re Marzocchi*, 439 F.2d 220, 223 (CCPA 1971). Therefore, absent evidence to the contrary, the Examiner <u>must</u> accept Applicant's asserted utility. As such, the Examiner's rejection of claims 1, 2 and 10 under 35 U.S.C. § 112, first paragraph is not proper. Reconsideration and withdrawal is respectfully requested.

VI. The Rejection of Claims 1, 2 and 10 under 35 U.S.C. § 112, First Paragraph

In the Office Action, at pages 5-7, the Examiner has rejected claims 1, 2 and 10 under 35 U.S.C. § 112, first paragraph, for allegedly failing to reasonably convey to one skilled in

the art that the inventors had possession of the claimed invention at the time the application was filed. Applicants respectfully traverse this rejection.

In support of this rejection the Examiner asserts:

> The specification discloses SEQ ID NO: 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605 which corresponds to the cDNA exhibiting homology to the a [sic] glutamyl tRNA reductase enzyme. SEQ ID NO: 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605 meet the written description provisions of 35 USC 112, first paragraph. However, it is not apparent from the specification that the claimed SEQ ID Numbers comprise a complete open reading frame and thus, claims 1-2 and 10 are directed to encompass sequences that hybridize to SEQ ID NO: 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605, corresponding sequences from other species, mutated sequences, allelic variants, sequences that have a recited degree of identity (similarity, homology), and so forth. None of these sequences meet the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Office Action, page 5, lines 5-15. Applicants disagree with these assertions.

An adequate written description of a genus of nucleic acids, as recited in claims 1 and 10, may be achieved by either "a recitation of a representative number of [nucleic acid molecules], defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus." *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568-69 (Fed. Cir. 1997). The feature relied upon to describe the claimed genus must be capable of distinguishing members of the claimed genus from non-members. *Id.*

SEQ ID Nos. 586, 590, 594, 596, 597, 599, 600, 601, 604, and 605 and their complements, are members of the claimed genera of claims 1 and 10, sharing common features with all the members of the claimed group. The Examiner has admitted on page 5

of the Office Action, that the description of these nucleic acid molecules meets the written description requirements of 35 U.S.C. § 112, first paragraph. These common features (sequences) distinguish the members of the claimed genus from non-members. As such, one skilled in the art, using only these disclosed examples in the specification and claims, coupled with the knowledge of one of ordinary skill in the art, would be able to distinguish between those nucleic acid molecules that are encompassed by the claims of the invention and those that are not.

Applicants wish to remind the Examiner that the written description requirement of 35 U.S.C. § 112, first paragraph is met if, "a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing...even if every nuance of the claims is not explicitly described in the specification." *In re Alton,* 76 F.3d 1168, 1175 (Fed. Cir. 1996). It is clear that one of ordinary skill in the art, in light of the sequence information, would have understood that Applicants were in possession of the claimed nucleic acid molecules at the time the application was filed. Thus, claims 1, 2 and 10 satisfy the written description requirement of 35 U.S.C. § 112, first paragraph, as well as new claims 11-21. Reconsideration and withdrawal of the rejection of claims 1, 2 and 10 under 35 U.S.C. § 112, first paragraph is respectfully requested.

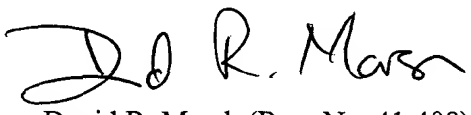
XII. Summary

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner

reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,



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Version with markings to show changes made

In the claims:

11. A substantially purified nucleic acid molecule, comprising a nucleic acid sequence selected from the group consisting of SEQ ID Nos: 586, 590, 594, 596, 597, 599, 600, 601, 604 and 605.

12. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 586.

13 The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 590.

14. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 594.

15. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 596.

16. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 597.

17. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 599.

18. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 600.

19. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 601.

20. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 604.

21. The nucleic acid molecule of claim 11, wherein said sequence is SEQ ID NO: 605.